

### **REMARKS**

The Official Action dated June 4, 2007 and the Advisory Action dated September 12, 2007 have been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claims 1 and 11 have been amended to incorporate limitations from original claims 9 and 16, respectively, and recite that the ratio ( $Mw_2/Mw_1$ ) is 1.35 to 5.00, as disclosed in the present specification at page 17, lines 4 to 7. Claims 1 and 11 have also been amended to recite that the weight average molecular weight ( $Mw$ ) of the ring-opening (co)polymer after the chain lengthening, whose molecular weight has been increased by the chain-lengthening reaction, is 150,000 to 500,000, in accordance with the teachings of the present specification in the paragraph bridging from pages 15 and 16, and to recite that a molecular weight distribution ( $Mw/Mn$ ) represented by a ratio of a weight average molecular weight ( $Mw$ ) of the ring-opening (co)polymer, whose molecular weight has been highly increased by the chain-lengthening reaction, to a number average molecular weight ( $Mn$ ) thereof is 1.90 to 4.50, as disclosed in the present specification at page 17, lines 12 to 24. Finally, claims 1 and 11 have been amended to recite that the difference ( $T_2 - T_1$ ) is 5 to 30°C, in accordance with the teachings of the present specification at page 18, lines 4 to 20. Claims 5 and 18 have been amended to correspond with claims 1 and 11, respectively. Additionally, claims 4, 8, 9, 16, and 20 have been canceled from the application, and claims 10, 21, 23-25, 27 and 18 have been amended to change their dependency and/or for matters

of form. Since these changes are believed to avoid any introduction of new matter, entry of the amendments is believed to be in order and is respectfully requested.

As defined by claim 1, the present invention relates to a high-molecular weight aliphatic polyester, whose molecular weight has been highly increased by a chain-lengthening reaction of a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer with an oxazoline compound having at least two oxazoline ring structures in its molecule to the extent that a ratio ( $Mw_2/Mw_1$ ) of a weight average molecular weight ( $Mw_2$ ) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight ( $Mw_1$ ) of the ring-opening (co)polymer before the chain lengthening is 1.35 to 5.00.

The ring-opening (co)polymer has a weight average molecular weight of at least 30,000 before the chain lengthening and is subjected to the chain-lengthening reaction to produce the high-molecular weight ring-opening (co)polymer. The weight average molecular weight ( $Mw$ ) of the ring-opening (co)polymer after the chain lengthening, whose molecular weight has been increased by the chain-lengthening reaction, is 150,000 to 500,000. A molecular weight distribution ( $Mw/Mn$ ) represented by a ratio of a weight average molecular weight ( $Mw$ ) of the ring-opening (co)polymer, whose molecular weight has been highly increased by the chain-lengthening reaction, to a number average molecular weight ( $Mn$ ) thereof is 1.90 to 4.50. A difference ( $T_2 - T_1$ ) between a 1%-weight loss-starting temperature  $T_2$  on heating of the ring-opening (co)polymer after the chain lengthening and a 1%-weight loss-starting temperature  $T_1$  on heating of the ring-opening (co)polymer before the chain lengthening is 5 to 30°C.

As defined by claim 11, in the process for producing a high-molecular weight aliphatic polyester according to the present invention, the ring-opening (co)polymer and the oxazoline compound are subjected to the chain-lengthening reaction under conditions that the reaction temperature is not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 300°C, and the reaction time is 10 to 30 minutes. By the process, a high-molecular weight ring-opening (co)polymer having the above properties is obtained.

According to the present invention, high-molecular weight polyglycolic acid (polyglycolide), which is difficult to obtain by the ring-opening polymerization of glycolide, can be obtained by the chain-lengthening reaction using the oxazoline compound. The high-molecular weight polyglycolic acid having a weight average molecular weight of 150,000 to 500,000 obtained by the chain-lengthening reaction is excellent in mechanical strength and moreover markedly improved in heat resistance. In order to efficiently increase the molecular weight by the reaction with the oxazoline compound to provide the aliphatic polyester having a sufficiently high molecular weight, it is preferable that the ring-opening (co)polymer has a weight average molecular weight of at least 30,000 before the chain lengthening and is subjected to the chain-lengthening reaction to produce a high-molecular weight ring-opening (co)polymer. The polyglycolic acid obtained by the chain-lengthening reaction is markedly improved in heat resistance as compared with the polyglycolic acid obtained by the ring-opening polymerization as shown by the difference ( $T_2 - T_1$ ) of 5 to 30°C. Further, the polyglycolic acid obtained by the chain-lengthening reaction is markedly improved in processability by the fact that the molecular weight distribution ( $M_w/M_n$ ) is as broad as 1.90-4.50.

In the Official Action dated June 4, 2007, claims 1, 4, 5, 7-10, 21 and 22 were rejected under 35 U.S.C. §102(b) as being anticipated by the Matsumoto et al Japanese reference JP 2001/323056. Claims 11, 16-18, 20 and 23-28 were rejected 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. Finally, claims 1, 4, 5, 7-11, 16-18 and 20-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Bonsignore U.S. Patent No. 5,470,944 in view of Matsumoto et al.

These rejections are traversed and reconsideration is respectfully requested. The high-molecular aliphatic polyesters defined by claims 1, 5, 7, 10, 21 and 22 and the processes for producing a high-molecular weight aliphatic polyester defined by claims 11, 17, 18 and 22-28 are neither anticipated by Matsumoto et al nor rendered obvious over Matsumoto et al or over Bonsignore in view Matsumoto et al.

Submitted herewith is an English translation of Matsumoto et al, referred to in the following discussion. It is believed that this translation will facilitate the Examiner's understanding of the deficiencies in Matsumoto.

In the Official Action dated June 4, 2007, the Examiner asserted that Applicants' composition and reaction are identical to those of Matsumoto et al, whereby Matsumoto et al's reaction and product must inherently increase the molecular weight as presently claimed. Applicants' Request for Reconsideration under 37 C.F.R. 1.116 filed September 4, 2007 provided extensive arguments and reasoning as to why the process and product of Matsumoto et al do not inherently provide an increase in weight average molecular weight satisfying the ratio  $Mw_2/Mw_1$  of at least 1.35, or as claims 1 and 11 now require, satisfying the ratio  $Mw_2/Mw_1$  of 1.35 to 5.00. In the Advisory Action, the Examiner questioned Applicants' arguments and reasoning regarding the deficiencies in the teachings of Matsumoto et al with

respect to the claimed molecular weight increase. Particularly, in the Advisory Action, the Examiner stated that:

“Applicant’s arguments drawn to the specific viscosity are not convincing because the data itself does not make sense. When Matsumoto end caps the polymer, the molecular weight must increase. There is no disclosure, evidence or scientific reason that the molecular weight would decrease. Thusly, since Matsumoto discloses a decrease in specific viscosity the Examiner believes that the different interaction between the solution and newly end capped polymer must affect the viscosity readings. Matsumoto is using the specific viscosity readings to further compare the hydrolysis rate of the polymers when subjected to hot water. Matsumoto is not concerned with the molecular weight or a molecular weight increase to prove end capping has occurred. Matsumoto relies on carboxyl equivalents as proof end capping occurs. For these reasons the Examiner can not draw clear conclusions on Matsumoto’s examples. The rejection thusly stands.”

However, Matsumoto et al do not disclose the molecular weight of the end capped aliphatic polyester, and instead, the solution specific viscosity is used by Matsumoto et al as an index to molecular weight changes. Example 1 of Matsumoto shows that poly(L-lactic acid), whose carboxyl end groups were end capped by reacting poly(L-lactic acid) with an oxazoline compound, had a solution specific viscosity ( $\eta_r$ ) of 9.26 (see paragraph [0036] of the English translation). On the other hand, Comparative Example 1 of Matsumoto shows that the solution specific viscosity of poly(L-lactic acid), whose carboxyl end groups were not capped, was 9.12 (see paragraph [0048] of the English language translation). The ratio between the solution specific viscosities of both polymers is 1.02 ( $9.26/9.12 = 1.02$ ), and therefore the solution specific viscosity is only very slightly increased, and is not substantially changed, by the end capping by the oxazoline compound. Since the oxazoline compound is a compound having a very low molecular weight as compared with poly(L-lactic acid), the poly(L-lactic acid) which is end-capped by a small amount of the oxazoline compound does not significantly change its molecular weight.

On the other hand, Matsumoto et al show that when the end-capped poly(L-lactic acid) is hydrolized by the hot water treatment, its ester bond is cut to lower its molecular weight, thereby lowering its solution specific viscosity. That is, Matsumoto et al carry out, as an accelerated test for resistance to hydrolysis, “hot water treatment” wherein the aliphatic polyester is treated with water at 130°C. When an aliphatic polyester resin is subjected to hydrolysis, its ester bond is generally cut to lower its molecular weight. For example, in Example 1, the solution specific viscosity of the end capped poly(L-lactic acid) was lowered to 8.70 after a 1-hour hot water treatment and to 6.05 after a 2-hour hot water treatment (Table 1).

It has heretofore been attempted to improve the resistance to hydrolysis by a method of lowering a carboxyl group concentration in the aliphatic polyester. Matsumoto et al attempt to lower the carboxyl group concentration in the aliphatic polyester by capping a part or the whole of the carboxyl end groups of the aliphatic polyester by the oxazoline compound, and in turn improve the resistance to hydrolysis. The experimental results of Matsumoto et al clearly demonstrate that the end-capped poly(L-lactic acid) was hydrolyzed by the hot water treatment to lower its molecular weight and thus to lower its solution specific viscosity.

Accordingly, it is apparent that Matsumoto et al use the solution specific viscosity as an index to the molecular weight, and in Example 1 show only a slight increase in molecular weight by end capping but a significant decrease in molecular weight as a result of hydrolysis.

Example 2 of Matsumoto shows that the solution specific viscosity of the poly(L-lactic acid) end-capped by the oxazoline compound EPC was 8.23 (see paragraph [0038] of

the English translation). A ratio between solution specific viscosities of this end-capped poly(L-lactic acid) and the non-end-capped poly(L-lactic acid) of Comparative Example 1 is 0.90 ( $8.23/9.12 = 0.90$ ). The reason for a reduction in the solution specific viscosity is not apparent from the teachings of Matsumoto et al. Applicants hypothesize that a decomposition reaction may have occurred upon the end-capping reaction, although it is not necessarily clarified from Matsumoto et al's description of Example 2. However, the fact that the solution specific viscosity of the end-capped poly(L-lactic acid) of Example 2 is lowered clearly demonstrates to one of ordinary skill in the art that a significant chain-lengthening reaction is not caused by the process of Matsumoto et al. In fact, the solution specific viscosity ratio near 1, as 0.90, demonstrates that the molecular weight of the poly(L-lactic acid) is not greatly changed by the end-capping reaction.

Accordingly, Matsumoto et al demonstrate, by using the solution specific viscosity values, that 1) the molecular weight of the aliphatic polyester is not changed by the end-capping reaction and only a carboxyl end group-capping reaction proceeds, and 2) the end-capped aliphatic polyester is hydrolyzed by the hot water treatment to greatly lower its molecular weight.

Matsumoto et al show, by comparison between Example 1 and Comparative Example 1, that the end-capped poly(L-lactic acid) better retains its solution specific viscosity after the hot water treatment was compared with uncapped poly(L-lactic acid), and therefore is excellent in resistance to hydrolysis. Accordingly, it is apparent that the solution specific viscosity and change thereof disclosed in Matsumoto et al are used as indexes to the molecular weight of the aliphatic polyester and the change thereof, respectively, and that the exemplary end capped polymers do not exhibit the significant increase in weight average

molecular weight sufficient to provide an  $Mw_2/Mw_1$  of 1.35-5.00 as required by claims 1 and 11.

In the Official Action of June 4, 2007, the Examiner asserted that Matsumoto et al carry their reaction to completion and thus the same reaction is happening for Matsumoto et al as is claimed by Applicants. In the Request for Reconsideration under 37 C.F.R. 1.116, Applicants argued that Matsumoto et al teach that unreacted oxazoline or oxazoline compound remains in the carboxyl end-capped aliphatic polyester product, whereby Matsumoto et al neither teach nor suggest that the oxazoline compound and/or oxazoline compound is completely reacted or both capping of the carboxyl end of the aliphatic polyester ester and a chain-lengthening reaction occur.

In the Advisory Action, the Examiner stated that:

“Applicant further argues that Matsumoto does not teach reacting the end-groups to completion, an argument the Examiner relied upon in the rejection. As evidence to this Applicant draws attention of [0021] wherein Matsumoto discloses the amount of unreacted end capping agent to be 2-5 wt%. The Examiner had previously used this amount as the amount of end capping agent added to the composition.

Though the Examiner erred in the position that 2-5 wt% of end capping agent is used in the composition, Matsumoto's examples show that the reaction was taken to near completion, specifically comparing Comp Ex 1 (33 eg/10-3 kg residual carboxyl groups) to Ex 6 (1 residual carboxyl equivalent after reaction with end capping agent). Further, in order to have 2-5 wt% excess end capping agent, one must use at least 2-5 wt% of said agent in the composition. Which meets the compositional requirements of Applicant's Claims. Matsumoto does disclose fully reacting the composition, as evidenced by Ex 6.”

However, neither end capping all of the carboxyl end groups nor using an excess of oxazoline compound or oxazoline compound for such end capping evidences the occurrence of a chain-lengthening reaction causing a significant increase in weight average molecular weight sufficient to provide an  $Mw_2/Mw_1$  as required by claims 1 and 11. Matsumoto et al



disclose an aliphatic polyester obtained by capping a part or all of the carboxyl end groups of an aliphatic polyester by an oxazoline compound (claim 1). However, the fact that all of the carboxyl end groups of the aliphatic polyester are capped by the oxazoline compound does not mean that the oxazoline compound is used as a chain-lengthening agent and Matsumoto et al provide no teaching in this regard.

Matsumoto et al do not provide sufficient detail regarding their examples to teach that a chain length extending reaction occurs. For example, in Example 1 of Matsumoto et al, a description of the conditions for the end-capping reaction is omitted. While Example 2 of Matsumoto et al describes that EPC was used as the oxazoline compound, and “heated and melted EPC was fed into a twin-screw kneader extruder at a cylinder temperature of 220°C while weighing it so as to give a ratio of PLLA : EPC = 90.00 : 10.00 (by weight), thereby reacting both components to obtain PLLA chips, whose carboxyl end groups were capped, and which had a  $\eta_r$  of 8.23” there is no description of the kneading time. Accordingly, these examples of Matsumoto et al do not disclose specific reaction conditions or the kneading time in the twin-screw kneader extruder. Therefore, there is no basis to assert that a chain length extending reaction occurs. To the contrary, the Matsumoto et al disclosure itself demonstrates that the carboxyl end groups of the aliphatic polyester are only capped by the reaction with the oxazoline compound, and a chain- lengthening reaction bringing a marked increase in molecular weight does not occur.

Applicants remind the Examiner that it is the burden of the Examiner to show that a prior art reference discloses all of the limitations necessary to inherently result in a product as claimed. MPEP §2112. The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or

characteristic, *In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q. 2d 1955, 1957 (Fed. Cir. 1993). In view of the deficiencies in the general teachings of Matsumoto et al and the deficiencies in the exemplary teachings of Matsumoto et al, it is clear that Matsumoto et al do not provide sufficiently specific teachings for the Examiner to meet this burden.

Moreover, as Matsumoto et al recommend that unreacted oxazoline compound remains in the end-capped aliphatic polyester for sustaining the resistance to hydrolysis, one skilled in the art will recognize that the reaction conditions used by Matsumoto et al are such that the whole amount of the oxazoline compound does not react and/or an amount of the oxazoline compound in excess of that needed for end capping is used. In either case, it is necessary to adopt such reaction conditions so that reactions other than the end-capping reaction do not occur. Thus, severe reaction conditions in which the oxazoline compound is ring-opened to show behavior of living polymerization, resulting in chain lengthening reaction, are avoided in order for unreacted oxazoline to remain in the end-capped polyester.

In the present invention, the chain-lengthening reaction is induced by adopting severe reaction conditions comprising a combination of a reaction temperature of not lower than the melting temperature of the ring-opening (co)polymer of glycolide, but not higher than 300°C, and a reaction time of 10 to 30 minutes. Under high-temperature conditions, an oxazoline compound is ring-opened by cutting of an O-C bond between the 5-position carbon atom and an oxygen atom in the oxazoline ring, and a carboxyl group of the ring-opening (co)polymer of glycolide is bonded to the 5-position carbon atom. When an oxazoline compound having 2 or more oxazoline rings is used, and severe reaction conditions as described above are adopted, the plurality of oxazoline rings in one oxazoline compound are ring-opened to cause the chain-lengthening reaction, achieving the significant increase in the molecular weight of

the ring-opening (co)polymer of glycolide, unlike the simple end-capping reaction of the oxazoline compound of Matsumoto et al. While Matsumoto et al also disclose that all of the carboxyl end groups of the aliphatic polyester may be capped, this does not mean that a chain-lengthening reaction by the oxazoline compound is caused by the end-capping reaction to result in a molecular weight increase as presently claimed. Matsumoto et al provide no such teaching of a chain-lengthening reaction and such is not inherent in the teachings of Matsumoto et al.

Finally, in the Request for Reconsideration, Applicants noted that the specific molecular weight ranges taught by Matsumoto et al are with respect to polylactic acid and not polyglycolic acid. Applicants also noted the deficiencies in the teachings of Bonsignore with respect to polyglycolic acid. In the Advisory Action, the Examiner stated that:

“Applicant argues the MW ranges disclosed in [0010] of Matsumoto are for polylactic acid and not polyglycolic acid, as required by the Claims. Though true, Matsumoto discloses polylactic and polyglycolic acid to be functional equivalent polymers to be used in the invention, and thusly one would use the same MW ranges disclosed for the polylactic acid. Applicant draws attention to the lower MW polyglycolic acid used in the examples, however the Examiner notes that the patent cannot be limited to the examples. The position of the Examiner is that one would use the ranges taught of the polylactic acid since polylactic acid and polyglycolic acid are functional equivalents.”

While polylactic acid and polyglycolic acid are like compounds in that they are aliphatic polyesters having a carboxyl group at their terminals, they are not common, however in range of their molecular weights. Applicants submit that there is no evidence of record supporting the Examiner’s assertion that the molecular weight ranges as disclosed for polylactic acid are applicable to polyglycolic acid. Matsumoto et al do not provide any teaching that polylactic acid and polyglycolic acid have equivalent molecular weights. Further, according to the ring-opening polymerization of glycolide, a ring-opening polymer

(polyglycolic acid) having a weight average molecular weight of at least 30,000 can be obtained. It is generally very difficult to obtain a ring-opening polymer having a high molecular weight exceeding 30,000. On the other hand, Bonsignore merely mentions polyglycolic acid is conventionally prepared by condensation polymerization or ring-opening polymerization and is environmentally compatible because it degrades to glycolic acid. No other mention of polyglycolic acid is made and particularly no teaching or suggestion for production of high molecular weight polyglycolic acid is disclosed by Bonsignore.

Importantly, Matsumoto et al and Bonsignore do not disclose a high-molecular weight polyester composed of a ring-opening (co)polymer of glycolide obtained by chain lengthening by an oxazoline compound, particularly having the various properties recited in claim 1 and markedly improved in mechanical strength, heat resistance and processability. Further, Matsumoto et al and Bonsignore do not disclose a process for subjecting the ring-opening (co)polymer of glycolide to the chain-lengthening reaction with the oxazoline compound under the reaction conditions recited in claim 11 of the present application, and do not teach or suggest that a high-molecular weight polyester having the above-described various properties may be obtained by such a process. It is therefore submitted that the high-molecular weight aliphatic polyester and production process thereof defined by the present claims are neither anticipated by nor rendered obvious over Matsumoto et al and are not rendered obvious over the combination of Bonsignore and Matsumoto et al.

It is believed that the above, together with the arguments set forth in detail in the Request for Reconsideration Under 37 C.F.R. 1.116 filed September 4, 2007, demonstrate the patentability of present claims 1, 5, 7, 10, 11, 17, 18 and 21-28, and place the present

application in condition for allowance. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 04-1133.

Respectfully submitted,

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